



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,597	04/15/2004	Stephen J. Pandol	034047.021.1	7147

7590 06/25/2008
Suzannah K. Sundby, Esq.
Smith, Gambrell & Russell, LLP
1850 M Street, NW #800
Washington, DC 20036

EXAMINER

PAGONAKIS, ANNA

ART UNIT	PAPER NUMBER
----------	--------------

1614

MAIL DATE	DELIVERY MODE
-----------	---------------

06/25/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/824,597	Applicant(s) PANDOL ET AL.	
	Examiner ANNA PAGONAKIS	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11 sheets, 2/29/2008; 1 sheet, 2/29/2008, 4 sheets, 2/29/2008</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's reply filed 2/29/2008 has been received and entered into the present application.

As reflected by the attached, completed copy form PTO/SB/08A (17 pages total), the Examiner has considered the cited references.

Claims 37-46 are pending. Accordingly, claims 1-36 have been cancelled and claims 37-46 have been added, no claims have been amended.

Rejections and objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Information Disclosure Statement

Documents with no date of publication were not considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 37-46 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Art Unit: 1614

The specification discloses chemicals, such as rottlerin which meet the written description and enablement provisions of 35 USC 112, first paragraph. However, claims 37 and 46 are directed to encompass derivatives, which only correspond in some undefined way to specifically instantly disclosed chemicals. None of these derivatives meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what they are and chemical structures are highly variant and encompass a myriad of possibilities. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of the above specifically disclosed chemical structures, the skilled artisan cannot envision the detailed chemical structure of the encompassed derivatives, analogs, etc., regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The chemical structure itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence. Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

Therefore, only the above chemically structurally defined chemicals, but not the full breadth of the claim(s) meet the written description provision of 35 USC § 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is

Art Unit: 1614

reminded that Vas-Cath makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision. (See page 1115.)

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 37-46 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. The term "derivative" in claim 37 is a relative term that renders the claim indefinite. In particular, the term "derivative" does not particularly point out the degree or type of derivation that a given compound may have in relation to the parent compound and still be considered a "derivative" as intended by Applicant. Applicant has failed to provide any specific definition for those terms in the present specification. Lacking a clear meaning of the term "derivative," the skilled artisan would not be reasonably apprised of the metes and bounds of the subject matter for which Applicant seeks patent protection. Words and phrases in the claims must be given their "plain meaning" as understood by one having ordinary skill in the art unless defined by Applicant in the specification with "reasonable clarity, deliberateness and precision" (MPEP 2111.01). Here, Applicant's definition of "derivative" is not reasonably clear, deliberate or precise because the mere statement of the use of an analog or derivative does not specify what other compounds may be considered rotterin derivatives. That is, the definition is presented in a non-limiting manner. Thus, the identity of those compounds that are included or excluded by the term "derivative" is open to subjective interpretation and such is inconsistent with the tenor and express requirements of 35 U.S.C. 112, second paragraph.

Applicant's Response

Applicant's representative directs the Examiner to the definition of a rottlerin "derivative" on page 43, paragraph 171 of the specification as originally filed. Further, Applicant's representative contend that the scope and meaning of derivative is clear and definite.

Response to Applicant's Arguments

Various chemical structures of rottlerin derivatives are provided by Applicant on page 43, paragraph 171 of the instant specification. Examiner contends that the prior art indicates that organic synthesis is unpredictable and difficult. In fact, Mukaiyama states that despite elucidation of reaction mechanisms and synthetic pathways, organic synthesis is still an unpredictable art (Pure & Appl. Chem. Vol. 69, No. 2, pp.257-258, 1997). Applicant has failed to provide adequate direction and disclosure as well as no working example and guidance as to how to prepare any of rottlerin derivatives.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 39-40 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

There seems to be multiple polyphenols in the claims but it is not clear under 35 U.S.C. 112, second paragraph, which one is meant by "the polyphenol" in claim 39.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 37-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al. (US 5,821,072) and Gschwendt (Biochem Biophys Res Commun, 1994) and Mouria (Int. J. Cancer, 98, 761-769, 2002).

Schwartz et al. teach an invention for enhancing therapy in a tumor bearing subject comprising administering to the subject an effective amount of a specific protein kinase C inhibitor capable of potentiating apoptosis in tumor cells during or prior to the treatment of an antitumor therapeutic agent (column 2, lines 56-61). The tumor can be a pancreatic cancer (column 3, line 14).

Gschwendt et al. teach of rottlerin as a novel protein kinase inhibitor which specifically inhibit PKC. Additionally it is taught that rottlerin can differentiate between PKC isozymes such as delta, epsilon, eta and zeta. The chemical structure of rottlerin might serve as a basis for the development of novel inhibitors with improved selectivity for distinct PKC isoenzyme such as PKC delta.

Art Unit: 1614

Mouria et al. teach that the effects of genistein was investigated on pancreatic carcinoma cells (abstract). Inhibitory effects of genistein on the development of metastatic lesions and the growth of the primary tumor in the same model of pancreatic cancer was observed (bridging pages 763-764). Genistein is also known to stimulate both apoptosis and caspase activation (page 765). Finally, the authors conclude that the genistein causes apoptosis in pancreatic cancer cells (page 766, column 2, paragraph 4).

One of ordinary skill in the art would have a reasonable expectation of success that rottlerin, a known PKC inhibitor would be effective against pancreatic cancer. Such success is expected since a protein kinase C inhibitor is known for the treatment of pancreatic cancer, Schwartz et al., and rottlerin is a known PKC inhibitor, Gschwendt et al. It would further be obvious to one of ordinary skill in the art to additionally administer genistein which is known for the treatment of pancreatic cancer. One of ordinary skill in the art would have been motivated to combine the references since as combined would teach the invention as claimed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNA PAGONAKIS whose telephone number is (571)270-3505. The examiner can normally be reached on Monday thru Thursday, 9am to 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1614

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AP

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614